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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,965	04/15/2004	Kenneth T. Heruth	1023-361US01	8233
28863 7590 08/23/2007 SHUMAKER & SIEFFERT, P. A. 1625 RADIO DRIVE SUITE 300 WOODBURY, MN 55125			EXAMINER GEDEON, BRIAN T	
			ART UNIT 3766	PAPER NUMBER
			MAIL DATE 08/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/825,965	Applicant(s) HERUTH ET AL.	
	Examiner Brian T. Gedeon	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-29 and 31-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47-49, 69-76 and 79-82 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12, 16-29, 31-35, 40-46, 77 and 78 is/are rejected.
- 7) ☒ Claim(s) 13-15 and 36-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/9/07 and 7/30/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9 July 2007 has been entered.

Information Disclosure Statement

2. The information disclosure statements (IDS) submitted on 9 July 2007 and 30 July 2007 was filed after the mailing date of the Notice of Allowance on 4 April 2007. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

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applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-6, 8-12, 16-29, 31-35, 40-46, 77 and 78 are rejected under 35

U.S.C. 102(e) as being anticipated by DiLorenzo (US Patent no. 6,819,956).

In regard to claims 1, 4-6, 8-10, 16-18, 22, 27-29, 31-33, 40-43, 77 and 78, DiLorenzo describe a neurological control system that delivers neural modulation signals to the nervous system. The system senses and quantifies patient activity (e.g., tremor resulting from a movement disorder) and derives a quantitative representation of the level or state of a particular disease, col 4 lines 49-57. An accelerometer array 52 measures the tremor activity. Threshold discriminators 126, 128, 130, 132, and 134, are used to provide a classification of the activity levels of the measured tremor based on threshold criteria, col 30 lines 1-5 and figure 5. The tremor activity levels then used to estimate a disease state of the patient, figure 5. Knowledge of the disease state allows for adjustments in therapy parameters (e.g., pulse width, amplitude, frequency etc), col 12 lines 23-38. The Examiner considers that the therapy adjustment based on the tremor activity/disease state to comprise the "associating" of activity levels with therapy sets since the activity level determines what set of therapy parameters (i.e., pulse width, amplitude, and frequency) is applied. DiLorenzo determine therapy set parameters based on activity level in order to prevent under treatment (i.e., when measured tremor amplitudes exceeds a desirable threshold), or overtreatment (i.e., excess stimulation), col 38 lines 51-57.

In regard to claims 2 and 25, DiLorenzo suggests bandpass filtering, col 4 lines 31-37.

In regard to claims 3 and 26, DiLorenzo determines disease states of patients in which it is taught that a disease state includes intrinsic disease states, which include patient wakefulness, col 39 line 64 – col 40 line 17.

In regard to claims 11, 12, 34, and 35, DiLorenzo measures a physiological parameter, such as muscular activity, through an EMG, col 9 lines 9-23.

In regard to claims 19-21 and 44-46, the device of DiLorenzo is an intracranial - stimulator (i.e., and implantable neurostimulator), col 6 lines 37-39.

In regard to claims 23 and 24, the system of DiLorenzo has a signal process 71 for conditioning sensed signals, and is implemented in a microprocessor, col 15 line 63 – col 16 line 5.

Allowable Subject Matter

5. Claims 47-49, 69-76 and 79-82 are allowed.
6. Claims 13-15 and 36-39 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. The above claims are allowed or objected to as being allowable in view that the prior art fails to teach that the association of therapy parameters sets and activity levels involves predetermined ordered lists of the associated values.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian T. Gedeon whose telephone number is (571) 272-3447. The examiner can normally be reached on M-F 8:30-5:00.

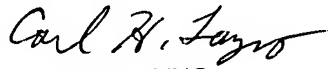
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brian T. Gedeon
Patent Examiner
Art unit 3766

BTG

Angela D. Sykes
Supervisory Patent Examiner
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CARL LAYNO
PRIMARY EXAMINER